





















- problems with blood flow in the liver,
- increased hairiness,
- thirst, fall, feeling of tightness in your chest, decreased mobility, ulcer,
- muscular weakness,
- echocardiogram abnormal, liver failure, narrowing of the bile vessel,
- painful urination with blood in the urine,
- increase of fat tissue.

*Not known (frequency cannot be estimated from the available data):*

- weight decrease,
- fainting,
- respiratory distress,
- mouth ulcers,
- fatty liver,
- hot flushes,
- multi-organ failure,
- transplant rejection.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### **Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of GRAFOLIN.



The 1 mg capsule shell contains FD & C Blue 1 (E133), gelatin, iron oxide yellow (E172) and titanium dioxide (E171).

The 5 mg capsule shell contains D & C Red 28, D & C Yellow 10 (E104), FD & C Blue 1, gelatin, and titanium dioxide (E171).

### **What GRAFOLIN looks like and contents of the pack**

GRAFOLIN 0,5 mg: White to off white powder filled in size 5 hard gelatin capsules with red opaque cap & red opaque body printed SAL on cap and 720 on body.

GRAFOLIN 1 mg: White to off white powder filled in size 5 hard gelatin capsules with green opaque cap & green opaque body printed SAL on cap and 721 on body.

GRAFOLIN 5 mg: White to off white powder filled in size 4 hard gelatin capsules with teal opaque cap & teal opaque body printed SAL on cap and 722 on body.

### **Contents of the pack**

HDPE container: 100 capsules are packed in a transparent, round 50 cc HDPE container closed with a white, opaque plastic cap.

Blister pack: 10 capsules are packed in aluminium foil (PVC/PVDC) blisters. 10 of such blisters will be packed in a printed carton.

Pack size: 100 capsules.

### **Holder of Certificate of Registration**

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**This leaflet was last revised in**

